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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/117,380 01/27/99 FRIDKIN

M FRIDKIN=1

HM22/0227

EXAMINER

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WASHINGTON DC 20001

HUTSON, R

ART UNIT	PAPER NUMBER
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1652

14

DATE MAILED:

02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/117,380	Applicant(s) Fridkin et al.
Examiner Richard Hutson	Group Art Unit 1652



Responsive to communication(s) filed on Dec 12, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 835 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

- Claim(s) 1-9, 12, and 13 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 1-9, 12, and 13 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

Applicants amendment of claim 1 is acknowledged. Claims 1-9, 12 and 13 are still at issue and are present for examination.

Applicants' arguments filed on 12/12/2000, paper No. 13, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

#### ***Claim Rejections - 35 USC § 112***

1. Claims 1 , 2-9, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants amendment of claim 1(ix) to recite "... but not including the entire CRP..." is not supported by the specification and is thus considered new matter.

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Yavin et al. (Letters in Peptide Science 2: 7-16, 1995).

The rejection is stated in the previous office action.

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Applicants traverse this rejection on a number of different basis: first applicants have amended the claim such that claim 1(ix) recites "... but not including the entire CRP..." This amendment of claim 1 in and of itself does overcome the rejection based on the "entire CRP" taught by Yavin et al. although as discussed above this amendment introduces additional 112 1st paragraph issues.

The rejection is maintained on the basis that Yavin et al. teach the isolation of peptide fractions generated from CRP by lysosomal enzyme digestion and Yavin et al. were in possession of additional fragments of CRP besides those identified in Table 1 that meet the limitation of claim 1 (ix), reciting a peptide obtained by elongation of a peptide (i) to (viii) at the N- and /or C-terminal, claim 1 and 2. The full-length CRP peptide was the starting material for the lysosomal enzyme digestions, and while Yavin et al. does not teach the identification of those fragments which meet the above limitation it is believed that such a fragment exists in the RP-HPLC profile in Figure 1(a) based on fact that not all of the CRP peptide will be "completely" digested and there exist many fragments that are a result of "incomplete" digestion. Further each of these "fractions" are considered to be isolated. HPLC fractionation clearly constitutes isolation.

It is noted that applicants further traverse this rejection on the basis that the examiners previous assertion that the entire CRP will inhibit the enzymatic activity of hLE **and/or** hCG is incorrect based on the disclosure on page 3, line 13 of the instant specification which states that CRP as a whole protein was reported to have no inhibitory effect on hLE. Based on this the applicants assert that the claim only covers peptides capable of inhibiting *in vitro* the enzymatic

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activity of hLE and/or hCG, and therefore they do not comprehend CRP. Since applicants have disclosed the relationship of CRP **only to hLE**, it still remains a reasonable assertion that CRP has an inherent ability of inhibiting hCG and the claim drawn to an isolated peptide capable of inhibiting in vitro the enzymatic activity of human Leukocyte Elastase (hLE) **and/or** human Cathepsin G (hCG) remains reasonable.

3. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Shepard et al. (J. Immunol. 145 (5): 1469-1475, 1990).

This rejection is stated in the previous office action.

Applicants traverse this rejection as above Yavin et al. rejection on a number of different basis. As above this argument is also found non-persuasive for the same reasons as stated above.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yavin et al. (Letters in Peptide Science 2: 7-16, 1995).

This rejection is stated in the previous office action.

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6. Claims 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shepard et al. (J. Immunol. 145 (5): 1469-1475, 1990).

This rejection is stated in the previous office action.

Applicants traverse each of the above 103(a) rejections as above based on the assertion that neither Yavin et al. or Shepard et al. disclose any peptides falling within the scope of claim 1. This argument is not found persuasive for the reasons stated above under 102 rejection.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on M-F from 7:30 to 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy (Murthy), can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson, Ph.D.  
2/15/2001

  
**REBECCA E. PROUTY  
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